DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2014

TSO_3 Inc.
C/O Thomas Richard, Ph.D.
Consultant
IM3, Inc.
512F NE 81st Street, Suite 101
Vancouver, WA 98665

Re: K141698
Trade/Device Name: STERIZONE® CI+ Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Chemical Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 14, 2014
Received: November 17, 2014

Dear Dr. Richard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141698

Device Name
STERIZONE® CI+ Chemical Indicator

Indications for Use *(Describe)*

The STERIZONE® CI+ Chemical Indicator is a single-use process indicator intended to distinguish between processed and unprocessed packaged medical devices to be sterilized using the STERIZONE® VP4 Sterilizer. The device is intended for use only with the STERIZONE® VP4 Sterilizer, which has a single sterilization cycle ("Cycle 1"). Critical process parameters for Cycle 1 are summarized in Table 1.

The red stripe chemical indicator is located above the peach-colored stripe labeled as the "REFERENCE". After exposure to the Cycle 1 of the STERIZONE® VP4 Sterilizer, the chemical indicator color changes from red to peach-Reference color (or lighter).

Table 1. STERIZONE® VP4 Sterilizer – Cycle 1 process parameters

Hydrogen peroxide exposure					Ozone exposure		Nb of phases
Hydrogen peroxide solution	Chamber differential pressure set point	Time	Sterilant injected	Vaporizer set point / Chamber temperature	O_3 injection	O_3 dwell	
125-280 Solution™ (H_2O_2 50 wt%)	19 Torr	210-600 sec*	8.4-24 g*	120°C / 41 ±3°C	2 mg/L	5 min	2

* Vaporized hydrogen peroxide injection/exposure time (Dynamic H_2O_2 exposure step) varies with load composition and conditions. The quantity of vaporized hydrogen peroxide injected is directly related to the time required to reach a pressure differential of 19 Torr in the chamber, for load temperature ranging from 20°C to 26°C. If the H_2O_2 injection time is less than 210 seconds, or greater than 600 seconds, the cycle will abort.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ANNEX 2

5.0 510(k) Summary

5.1. Applicant's Name and Address and submission date

Applicant's Name and Address

TSO_3 Inc.,
2505, avenue Dalton, Québec (Quebec) Canada G1P 3S5

TSO_3 Contact Person, Telephone, FAX

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U.S. Contact

Contact: Thomas Richards, Ph.D. of IM3, Inc.
Phone: 503-415-0250
Email: tomami20x@gmail.com

Submission Date

December 10, 2014

5.2. Name of the device

Trade Name

STERIZONE® CI+ Chemical Indicator

Common Name

Chemical sterilization process indicator

Classification Name (if known)

Indicator, Physical/Chemical Sterilization Process

Regulatory Class

Class II under Sterilization Process Indicator in 21 CFR 880.2800 (b) by the General Hospital and Personal Use Devices Panel.
Product code: JOJ

5.3. Legally Marketed Equivalent Device Name(s)

Verify® V-PRO Chemical Indicator (Version 1A) (K091174)

5.4. Description of device

The STERIZONE® CI+ Chemical Indicator (CI+) is a Class 1 process indicator that conforms to ANSI/AAMI/ISO 11140-1: 2005(R)2010, and is intended to only be used with the STERIZONE® VP4 Sterilizer. The single pre-set cycle (Cycle 1) of the STERIZONE® VP4 Sterilizer utilizes vaporized hydrogen peroxide and ozone in a multiphase process, to rapidly sterilize a variety of reusable medical devices.

The CI+ chemical indicator consists of a polymeric material strip on which an indicator ink, a reference color and a varnish coating have been deposited. The CI+ provides a visual indication that a sterilization load has been exposed to the STERIZONE® VP4 Sterilizer Cycle 1. The indicator works by means of a chemical reaction, which results is a recognizable color change from red to peach (or lighter).

5.5. Indication for use

The STERIZONE® CI+ Chemical Indicator is a Class 1 process indicator intended to distinguish between processed and unprocessed packaged medical devices to be sterilized using the STERIZONE® VP4 Sterilizer. The device is intended for use only with the STERIZONE® VP4 Sterilizer, which has a single sterilization cycle ("Cycle 1"). Critical process parameters for Cycle 1 are summarized in Table 1.

The red stripe chemical indicator is located above the peach-colored stripe labeled as the "REFERENCE". After exposure to the Cycle 1 of the STERIZONE® VP4 Sterilizer, the chemical indicator color changes from red to peach-Reference color (or lighter).

Table 1. STERIZONE® VP4 Sterilizer – Cycle 1 process parameters

Hydrogen peroxide exposure					Ozone exposure		Nb of phases
Hydrogen peroxide solution	Chamber differential pressure set point	Time	Sterilant injected	Vaporizer set point / Chamber temperature	O_3 injection	O_3 dwell	
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* Vaporized hydrogen peroxide injection/exposure time (Dynamic H_2O_2 exposure step) varies with load composition and conditions. The quantity of vaporized hydrogen peroxide injected is directly related to the time required to reach a pressure differential of 19 Torr in the chamber, for load temperature ranging from 20°C to 26°C. If the H_2O_2 injection time is less than 210 seconds, or greater than 600 seconds, the cycle will abort.

5.6. Assessment of performances data

5.6.1. Summary of nonclinical performance tests

Performance testing was conducted to demonstrate the functionality of the STERIZONE® CI+ Chemical Indicator and general conformance with the requirements for Class 1 vaporized hydrogen peroxide sterilization indicators as detailed in ANSI/AAMI/ISO 11140-1:2005(R)2010.

Table 2. Summary of nonclinical tests performed to demonstrate Safety and Effectiveness of the STERIZONE® CI+ Chemical Indicator

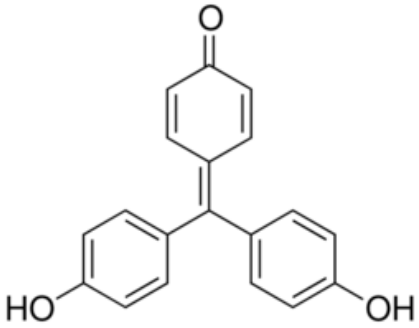
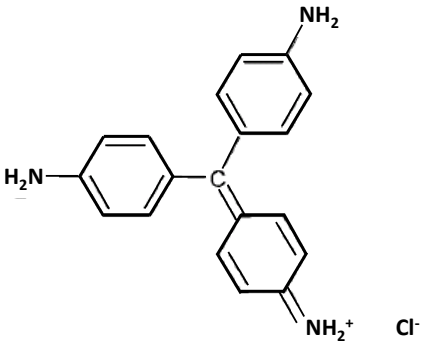
	Test	***Result***
1	CI+ Functionality	Passed
2	Shelf-life	Passed
3	Endpoint color stability	Passed
4	ISO 11140-1 compliance	Passed
5	Biocompatibility	Passed

5.7. Substantial equivalence

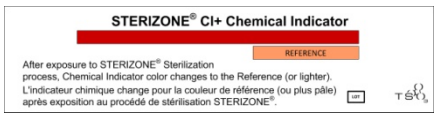
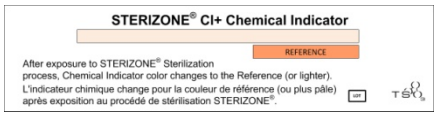
The STERIZONE® CI+ Chemical Indicator is substantially equivalent to the Verify® V-PRO Chemical Indicator (K091174). The CI+ and predicate device are both single-use process indicators intended to monitor sterilization cycles that utilize vaporized hydrogen peroxide as a primary sterilant. Furthermore, the CI+ and predicate device are identical in design, both utilizing a dye, which when exposed to hydrogen peroxide, changes color. The difference in endpoint color change between exposed and non-exposed indicators is minor, and does not raise different questions of safety and effectiveness.

Table 3. Comparison between the STERIZONE® CI+ Chemical Indicator and the Verify® V-PRO Chemical Indicator (K091174)

Feature	**STERIZONE® CI+ Chemical Indicator**	**Verify® V-PRO Chemical Indicator (Version 1A) (K091174)**
Intended Use	Single use sterilization process indicator	Single use sterilization process indicator
Indications for use	The STERIZONE® CI+ Chemical Indicator is a single-use process	A process indicator intended to distinguish between processed and

Feature	STERIZONE® CI+ Chemical Indicator	Verify® V-PRO Chemical Indicator (Version 1A) (K091174)
	indicator intended to distinguish between processed and unprocessed packaged medical devices to be sterilized using Cycle 1 of the STERIZONE® VP4 Sterilizer.	unprocessed units when placed within sterilization wraps, trays or pouches to indicate, through a visible change from magenta to yellow, when the device has been exposed to a V-PRO 1 Low Temperature Sterilization process (Lumen Cycle) or V-PRO 1 Plus Low Temperature sterilization process (Lumen and Non-Lumen cycle).
Endpoint specifications - Distinctive Color Change	Red stripe changes to 'peach' (reference) stripe or a lighter color when exposed to the STERIZONE® VP4 Sterilizer.	Magenta spot changes to yellow (reference) when exposed to the Amsco V-PRO 1 or V-PRO 1 Plus Low Temperature Sterilization system
Indicator agent	Rosolic acid base 	Pararosaniline base[1] 
Substrate	Polymer (Polypropylene)	Polymer (Polypropylene)
Technology features	The molecule structure comprises three conjugated rings. Chromophore functional group is associated with the molecule. The energy difference between two different molecular orbitals in the chromophore is within the visible spectrum. If the bond is broken due to H_2O_2 exposure, the color changes.	Same

[1] US Patent 2009/0023217, assigned to Steris, describes the use of pararosaniline base (a triphenylmethane dye) as an indicator agent for exposure to hydrogen peroxide.

Feature	STERIZONE® CI+ Chemical Indicator	Verify® V-PRO Chemical Indicator (Version 1A) (K091174)
Principles of operation	Redox Reaction. C=C and C=O are the two double bonds present in the chromophore of the molecule. The initial color is affected by the C=O group, which is part of the overall conjugated system. When exposed to H_2O_2, the C=C is broken due to the action of HO_2^- (H_2O_2 anion). This results in a color change.	Redox Reaction. C=C and C=N are the two double bonds present in the chromophore of the molecule. The initial color is affected by the C=N group, which is part of the overall conjugated system. When exposed to H_2O_2, the C=C is broken due to the action of HO_2^- (H_2O_2 anion). This results in a color change.
Sterilization method and cycles	STERIZONE® VP4 Sterilizer utilizes both vaporized hydrogen peroxide and ozone in a single pre-set cycle (Cycle 1), which is intended for general instruments, single-channel flexible endoscopes, and rigid-channel devices including single-channel and double-channel rigid endoscopes.	V-PRO 1 Low Temperature Sterilization process utilizes vaporized hydrogen peroxide in multiple cycle configurations (Lumen Cycle and Non-Lumen Cycle), which are intended for different medical devices.
Dedicated Use	Yes, in the STERIZONE® VP4 Sterilizer	Yes, in the V-PRO® Sterilization system
CI can be used both internally (within package) and externally	Yes	Yes
Ease of Results Interpretation	Reference color for end point is a stripe identified “REFERENCE”. No external color reference is required.	Reference color for end point is a yellow colored spot printed aside of the indicator ink spot. No external color reference is required.
Storage Conditions	Dry area, ambient temperature of 15º to 30º C	Temperature: 6º to 30º C RH: 30 to 60%
Picture of the device Unprocessed		
Processed		

5.8. Overall Performance Conclusions

Performance tests demonstrate that the STERIZONE® CI+ Chemical Indicator is suitable to distinguish between processed and unprocessed packaged medical devices to be sterilized using Cycle 1 of the STERIZONE® VP4 Sterilizer. The STERIZONE® CI+ Chemical Indicator is as safe and as effective as the Verify® V-PRO Chemical Indicator (Version 1A) (K091174).

Both the subject and predicate indicators have the same intended use, technical characteristics and performance. Based on the non-clinical performance testing data the subject device has proven to be as safe and effective as the predicate device (Verify® V-PRO Chemical Indicator (Version 1A) (K091174), when monitoring the Cycle 1 sterilization process for the STERIZONE® VP4 Sterilizer.